# *Frequently Asked Questions About Waste Pharmaceuticals*

## Management of containers that held P listed wastes:

### Do containers and packaging that held P listed pharmaceuticals have to be triple rinsed?

The Virginia Hazardous Waste Management Regulations (VHWMR) do not provide any exemptions or exclusions from the requirement for triple rinsing of containers that held P-listed waste such as warfarin or nicotine to be considered empty.

**VHWMR 40 CFR § 261.7(b)(3) states that "** (3) A container or an inner liner removed from a container that has held an acute hazardous waste listed in §§ 261.31, 261.32, or 261.33(e) is empty if: (i) The container or inner liner has been triple rinsed using a solvent capable of removing the commercial chemical product or manufacturing chemical intermediate; (ii) The container or inner liner has been cleaned by another method that has been shown in the scientific literature, or by tests conducted by the generator, to achieve equivalent removal; or (iii) In the case of a container, the inner liner that prevented contact of the commercial chemical product or manufacturing chemical intermediate with the container, has been removed." Please see:
http://www.deq.virginia.gov/waste/wastereg60.html

EPA has further clarified the status of containers that once held pharmaceuticals that are on the "P- list" of commercial chemical products in 40 CFR 261.33(e) as well as approaches in counting the residue toward generator status in a November 4, 2011 Memorandum from Suzanne Rudzinksi. Please see:
http://www.deq.virginia.gov/waste/pdf/guidance/p_listed_pharmaceuticals_memo_ORCR_2011.pdf

See also:
http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/A84D28E4C573528E8525670F006C1BCC/$file/12946.pdf

## Nitroglycerine:

### Is discarded, unused medicinal nitroglycerine regulated as a hazardous waste?

Previously, unused discarded nitroglycerine would have been regulated as a hazardous waste because of the characteristic of reactivity. Medicinal nitroglycerine contains a listed chemical, P081 as the sole active ingredient. Sometime around 2002, EPA revised the mixture and derived-from rules [40 CFR 261.3(g)(1)] which stated that a waste listed solely for the characteristic of ignitability, corrosivity, or reactivity is not regulated as a hazardous waste if it does not exhibit any hazardous waste characteristic. Moreover, if the waste does not exhibit a characteristic at the point of generation, it is considered to

have never been a hazardous waste and does not need to meet land disposal restrictions (LDRs) (66 FR 27286, May 16, 2001). This revision is included in Virginia's current Hazardous Waste Management Regulation. See: http://www.deq.virginia.gov/export/sites/default/waste/pdf/part261.pdf Because P081 is listed solely for reactivity, and because it is presumed that medicinal nitroglycerine is not reactive, it would not be regulated as hazardous waste under the new federal rules, and also would not be subject to LDRs.

## Epinephrine salts:

### Are epinephrine salts regulated as a hazardous waste when disposed?

EPA has clarified that the P042 listing does not include epinephrine salts in a memo from Matt Hale, Director on October 15, 2007 titled "Scope of Hazardous Waste Listing P042 (Epinephrine)" and the Virginia DEQ is in agreement with EPA's clarification. This document may be viewed at: http://www.epa.gov/region1/healthcare/pdfs/EpiMemo_Final.pdf. The P042 listing does include epinephrine base and any waste meeting the listing would be regulated as acute hazardous waste.

http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/6a5dedf2fba24fe68525744b0045b4af!OpenDocument.

http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/1C1DEB3648A62A868525670F006BCCD2/$file/13718.pdf

## Nicotine Patches:

### What is the regulatory status of used and unused nicotine patches?

When an unused pharmaceutical waste containing a P-listed constituent is discarded or intended to be discarded, it must be managed as hazardous waste if the waste contains a sole active ingredient that appears on the P list, and it has not been used for its intended purpose. A sole active ingredient means that the listed chemical in the discarded pharmaceutical must be the only ingredient that performs the intended function of the formulation. Nicotine products that have not been used for their intended purpose would meet the listing. Additionally, unused nicotine patches and gum would be considered commercial chemical products, as are other hazardous waste pharmaceuticals, and not manufactured articles. Therefore, the listing would apply.

Nicotine patches and gum that have been used for their intended purpose would not meet the listing and could be managed as a solid waste.

http://www.epa.gov/waste/inforesources/pubs/hotline/92report/mar92.txt

http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/FE5517867B1011158525670F006C2C92/$file/14095.pdf

http://yosemite.epa.gov/osw/rcra.nsf/ea6e50dc6214725285256bf00063269d/B68B23A1BE4CC2CA852570750068861C/$file/13310.pdf

http://yosemite.epa.gov/osw/rcra.nsf/ea6e50dc6214725285256bf00063269d/31470587B8ACB2E28525670F006C28DA/$file/14012.pdf

http://www.epa.gov/oig/reports/1996/996sect3.htm

## Household Pharmaceutical Waste:

### How are pharmaceuticals generated by households regulated?

Waste generated by a household as defined by 40 CFR 261.4(b)(1) is not regulated as a hazardous waste, but is regulated under the Virginia Solid Waste Management Regulations. Household hazardous waste pharmaceuticals are excluded from regulation as a hazardous waste so there are no hazardous waste requirements (no storage, time frame, transportation, etc. requirements). EPA has said that the exclusion from the hazardous waste regulations carries on throughout the life of the waste stream so it remains excluded when collected and disposed of. Collections of household hazardous waste pharmaceuticals only have to comply with the solid waste regulations.

Please see: http://www.deq..virginia.gov/waste/wastereg80.html.

http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/7e46a5a100ca92e68525670f006bfe41!OpenDocument

## Management of Non RCRA Subtitle C Regulated Pharmaceuticals:

### How are non hazardous pharmaceuticals regulated?

Non hazardous pharmaceutical wastes would be considered a solid waste and are regulated under the Virginia Solid Waste Management Regulations. Please see: http://www.deq..virginia.gov/waste/wastereg80.html.

## Reverse Distribution:

### Can waste pharmaceuticals be returned through a reverse distributor?

There is no Virginia specific guidance on reverse distribution of pharmaceuticals. DEQ generally concurs with EPA's reverse distribution policies. Generators must bear in mind

that reverse distribution cannot be used in lieu of proper RCRA hazardous waste management, but may be a legitimate recovery option for a manufacturer's unused products. Reverse distribution does not generally apply to used, spent, damaged, contaminated or degraded materials or products otherwise in a state that differs significantly from their original product condition. Please see the link below in which EPA discusses reverse distribution systems as it pertains to pharmaceuticals.

http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/a3a7a7a8f297438b8525670f006be5d8!OpenDocument

## **Vaccine and preservative residue**:

Thimerosal residues in vaccines/syringes

The presence of mercury or mercury containing compounds may cause certain spent materials to be regulated as a RCRA Subtitle C hazardous waste when they are discarded. Although it is not considered a *listed* hazardous waste, the presence of sufficient thimerosal may cause any discarded materials containing it, or contaminated by it, to be regulated as a characteristic hazardous waste. The characteristic may be determined by generator knowledge of the waste or by a laboratory test procedure known as TCLP, the toxicity characteristic leaching procedure.

Discarded materials that exhibit greater than 0.2ppm Hg when tested in accordance with the TCLP are considered a *toxicity characteristic* hazardous waste. In determining this concentration dependent criteria, the entire waste sample should be tested. For a used syringe, it would include not only the residual thimerosal but also the weight of the syringe and other residues. Therefore, it is unlikely that used syringes would exhibit a characteristic unless they contained significant residual thimerosal. Nor would empty vials be expected to exhibit a toxicity characteristic. However, full vials of vaccine containing 50 ppm equivalent of mercury (50,000ppb as you've indicated) may indeed fail a TCLP toxicity characteristic. It is recommend that you contact the vaccine manufacturer to confirm if this is the case rather than go to the expense of having a representative sample tested.

Used syringes and needles may also be considered regulated medical waste if contaminated with body fluids. However, the hazardous waste regulations take precedent over regulated medical waste (RMW) if the material is a mixed RMW/HW. Regulated hazardous wastes may not be incinerated at a RMW disposal facility, but the hospital may use other infection control or treatment methods to render the waste non-infectious so that it may be handled as a RCRA HW.

For more information on hazardous waste identification and management in hospitals, and the RCRA Subtitle C hazardous waste program in general, please see these references:

http://www.epa.gov/Region2/healthcare/presentations/rcra.pdf
http://www.h2e-online.org/
http://www.epa.gov/epaoswer/general/orientat/

If you have any questions about waste identification, treatment/storage/disposal facilities, transporters, recycling, or specific regulatory requirements, please check with your DEQ Regional Office. http://www.deq.virginia.gov/regions/homepage.html

Please note that this is an instructional summary for compliance assistance purposes. Generators are encouraged to review the complete hazardous waste regulations and to check with appropriate DEQ staff if they have any questions about regulation applicability to their waste streams.

*Virginia Department of Environmental Quality*
*Hazardous Waste Compliance Coordinator*
*4/6/10*